NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008 | **Substance:** Tetracycline (oxytetracycline hydrochloride)

Committee: Crops √ **Livestock** ☐ **Handling** ☐ **Petition is for:** Adding Tetracycline (oxyteracycline hydrochloride) as plant disease control for all diseases on the crops registered by the U.S. EPA on the National List § 205.601(i)(10) (effectively removing the current annotation)

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) — **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes √	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes ☐	No √	N/A ☐
3.	Compatibility & Consistency	Yes ☐	No √	N/A ☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A ☐

B. Substance Fails Criteria Category: 2 & 3 Comments: Material only marginally satisfies Criteria #1. Fails Criteria #2 since other organically approved disease control options exist for peaches and nectarines. Export pear growers already achieving some measure of fireblight control without material. Fails Criteria #3 on compatibility with public perception that antibiotics are not used in organic production, and on consistency within the NOP regulations that do not allow antibiotic use in any other section.

C. Proposed Annotation (if any): _____

_____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): Add Tetracycline (oxytetracycline hydrochloride) as plant disease control for all diseases on the crops registered by the U.S. EPA on the National List §205.601(i)(10), removing current annotation.

Motion by: G. Davis *Seconded:* R. Delgado *Yes:* 0 *No:* 6 *Absent:* 1 *Abstain:* 0

Crops	X	Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling		Synthetic	X	Rejected[3]	X
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance voted to be added as "allowed" on National List to § 205._____with Annotation (if any) _____

_____

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

_____

Describe why a prohibited substance:_____

_____

3) Substance was rejected by vote for amending National List to § 205.601(i)(10)Describe why material was rejected: Material fails evaluation criteria 2 and 3 (See comments listed above in section B.

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Gerald Davis — **Committee Chair**

3/31/2008 — **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		TAP: Line 163-164
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TAP: Line 174-175
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TAP: Line 188-191
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		TAP: Line 200-202
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		No: TAP Line 210-212 Yes: Potential detrimental effects on soil bacteria. Short term effects on pond sediment microorganisms from veterinary tetracycline mentioned.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X	X		TAP: Line 217-223 Potential detrimental effects expected to be mitigated with proper use in orchard system See also Question #6
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X	X		TAP Line232-256 Toxicological studies on rodents show no adverse effects, except to a limited extent at extremely high dosages. Human medicinal use side effects and allergic reactions do occur.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TAP: Line 261-270 Degradation half-life varies from 30 days (freshwater) to 10 weeks in pond sediments. Adsorbed and inactivated in dry soils.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X	X		Chronic dietary intake and occupational exposure risks are considered to be negligible by EPA. EPA pesticide label regulation on minimizing allergic reaction risks concerning spray application workers. (TAP: Line 275-293)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance - Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X	X		Parent material formed by natural fermentation process. Material as formulated may or may not have undergone chemical change during manufacture.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X	X		See above- question #1. Tacit acknowledgement of chemical change during manufacture, as material is petitioned as a synthetic substance to be added to the National List.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		See above- question #1
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		Available natural biological control materials are not adequate to control the serious damage caused by the fireblight organism. Effective natural products containing Bacillus subtilis, B. pumilis and others available for stone fruit (nectarine and peach) disease control.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]	X			Peracetic acid for fireblight control is partially effective. Some Washington state pear growers (for European export) achieving some measure of fireblight control without tetracycline, which is not allowed by Euro. Organic rules. Hydrated lime is used in stone fruit for disease control. Copper fungicides only marginally effective due to phytotoxic properties on crop leaves and fruit. (TAP Line 314-330)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Apple and pear varieties exist with limited to some resistance against fireblight. Careful soil site selection (well drained) is useful in disease control. (TAP Line 342-343)

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance - Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Antibiotics of this type are disallowed for any other uses in the USDA/NOP regulations. Marketing claims of organic products of many kinds state that no antibiotics are used. Public perception to a high degree expects that no antibiotics are used.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;	X			
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance - _____

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?				
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				